

REMARKS

Reconsideration and reversal of the rejections expressed in the Office Action of September 28, 2004 are respectfully contended in view of the following remarks and the application as amended. The present invention relates to an ophthalmic fluid for topical application to a contact lens, wherein the ophthalmic fluid is arranged in use to provide a protective film intermediate a lipid layer of a tear film of an ocular substrate and a contact lens, the ophthalmic fluid including at least one specific glyceride.

Claims 1-15 were rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al., U.S. Patent No. 5,981,607. Ding et al. relates to an eye drop composition for alleviation of dry eye related symptoms in dry eye patients and contact lens wearers, which includes an emulsion of a higher fatty acid glyceride, polysorbate 80 and an emulsion stabilizing amount of Pemulen® in water suitable for topical application to ocular tissue.

At column 3 lines 32-38 of Ding et al., it is stated that the invention is: *"directed to an emulsion system which utilizes higher fatty acid glycerides but in combination with polysorbate 80 which results in an emulsion with a high comfort level and low irritation potential suitable for delivery of medications to sensitive areas such as ocular tissues as well as being suitable for alleviating dry eye symptoms."* There follows a statement of the invention which is directed to a non-irritating pharmaceutical composition comprising an admixture of an emulsifying amount of a higher fatty acid glyceride and polysorbate 80. At column 4 lines 57-60 of the reference, it is stated that the discovery on which the invention of Ding et al. is founded: *"relates to an emulsion of a higher fatty acid glyceride such as, for example, castor oil, corn oil, sunflower oil or light mineral oil and an emulsifier and dispersing agent, polysorbate 80."*

The specification then goes on to discuss the composition of polysorbate 80, which is a mixture of oleate esters of sorbitol and sorbitol anhydrides condensed with approximately 20 moles of ethylene oxide. Further, referring back to column 3 at line 54 onward it is stated that the weight ratio of castor oil to polysorbate 80 is between about 0.3 to about 30. Thus, it is clear that the polysorbate 80 is a substantial component of the emulsion of Ding et al.

Please note that the ophthalmic fluid of the present invention is not an emulsion. In particular, it does not contain polysorbate 80 or any compound of a similar nature to polysorbate 80. In contrast to Ding et al., in the present invention as claimed, the ophthalmic fluid consists essentially of a glyceride. Furthermore, it is clear from the examples of Ding et al. that it is intended that the emulsion be applied directly to ocular tissue so as to deliver a medication thereto. In fact, claim 1 of Ding et al. recites: "*A method for alleviation of dry eye related symptoms in dry eye patients and contact lens wearers, said method comprising topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80 and an emulsion stabilizing amount of Pemulen in water...*" In contrast, in the present invention the ophthalmic fluid is not applied directly to ocular tissue; the ophthalmic fluid is applied to an inner surface of a contact lens, as disclosed in the present specification at e.g., page 6, paragraph 1 and as presently claimed. Subsequently, the coated inside surface of the contact lens is applied to an ocular substrate. Therefore, there is no teaching, suggestion or motivation in Ding et al. to adopt the method of the present invention as claimed, and this rejection is overcome.

Claim 15 was rejected under 35 U.S.C. 101 and 35 U.S.C. 112, second paragraph; claims 1-15 were also rejected under 35 U.S.C. 112, first paragraph. The claims as amended overcome these rejections.

For all of the above reasons, it is respectfully contended that the solicited claims define patentable subject matter. Reconsideration and reversal of the rejections expressed in the Office Action of September 28, 2004 are respectfully requested. The Examiner is invited to call the undersigned if any questions arise during the course of reconsideration of this matter.

Respectfully submitted,

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